K072375 (1 of 2)

4.0 510(k) Summary

Date: August 6, 2007

DEC 13 2007

Sponsor of the 510(k)

Angiodynamics, Inc.
603 Queensbury Ave
Queensbury, NY 12801
Establishment Registration number 1319211
Contact: Brian Kunst, Vice President, Regulatory Affairs and Quality Assurance
518-798-1215, x1123

K072375 (P. 2 of 2)

Device Identification:

Proprietary Name:	Smartport CT MP Port Access System
Common Name:	Vascular access port
Classification Name:	Subcutaneous, implanted, intravascular infusion port & catheter
Classification Number:	21 CFR §880.5965
Classification Panel:	General Hospital
Product Code:	LJT
Regulatory Class:	II

Proprietary Name:	LifeGuard® CT Safety Infusion Set
Common Name:	Port Access Infusion set
Classification Name:	Set, administration, intravascular
Classification Number:	21 CFR §880.5440
Classification Panel:	General Hospital
Product Code:	FPA
Regulatory Class:	II

Legally marketed device to which equivalence is claimed:

C.R. Bard PowerPort, 510(k) K060812
Angiodynamics Smartport CT and LifeGuard Needle, 510(k) K062414
Vortex MP Vascular Access Port, 510(k) K033473, K032754

Intended Use / Indications

The Smartport CT MPPort Access System is indicated for any adult patient requiring repeated access of the vascular system or other selected body site, for the delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood.

The Smartport CT MP port can accommodate a 3 ml/sec injection rate of contrast agent when used with a 19 or 20 gauge power injectable infusion set.

The 19 or 20 gauge LifeGuard Infusion Set can accommodate power injection when used with Smartport CT ports.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Mr. Brian Kunst
Vice President, Regulatory Affairs and Quality Assurance
ANGIODYNAMICS, Incorporated
603 Queensbury Avenue
Queensbury, New York 12804

Re: K072375
Trade/Device Name: LifeGuard® CT Safety Infusion Set
Regulation Number: 21 CFR 880. 5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT, FPA
Dated: November 28, 2007
Received: November 29, 2007

Dear Mr. Kunst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: LifeGuard® CT Safety Infusion Set

Indications for Use:

The LifeGuard® CT Safety Infusion Set is indicated for use in the access of implanted vascular ports for the administration of fluids and drugs, as well as blood sampling.

The 20ga and 19ga LifeGuard® CT Safety Infusion Sets are also indicated for power injection of contrast media when used with Smartport CT power injectable port access systems.

Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072375